

1 CABINET FOR HEALTH AND FAMILY SERVICES

2 Office of Health Policy

3 (Amendment)

4 900 KAR 6:070. Certificate of Need considerations for formal review.

5 RELATES TO: KRS 216B.010, 216B.090 [~~216B.040~~], 216B.990

6 STATUTORY AUTHORITY: KRS 194A.030, 194A.050, 216B.040[(2)(a)1,]

7 NECESSITY, FUNCTION, AND CONFORMITY: KRS 216B.040(2)(a)1 requires the
8 Cabinet for Health and Family Services to administer Kentucky's Certificate of Need
9 Program and to promulgate administrative regulations as necessary for the program.
10 KRS 216B.040(2)(a)2 requires the cabinet to promulgate an administrative regulation
11 establishing the criteria for issuance and denial of certificates of need. This
12 administrative regulation establishes the requirements necessary for the consideration
13 for formal review of applications for the orderly administration of the Certificate of Need
14 Program.

15 Section 1. Definitions. (1) "Cabinet" is defined by KRS 216B.015(5).

16 (2) "Days" means calendar days, unless otherwise specified

17 (3) "Formal review" means the review of applications for certificate of need which
18 are reviewed within ninety (90) days from the commencement of the review as provided
19 by KRS 216B.062(1) and which are reviewed for compliance with the review criteria set
20 forth at KRS 216B.040 and in this administrative regulation.

21 (4) "Public information channels" means the Office of Communication and

Administrative Review in the Cabinet for Health and Family Services.

(5) "Public notice" means notice given through:

(a) Public information channels; or

(b) The cabinet's Certificate of Need Newsletter.

Section 2. Considerations for Formal Review. In determining whether to approve or deny a certificate of need, the cabinet's review of applications under formal review shall be limited to the following considerations:

(1) Consistency with plans.

(a) To be approved, a proposal shall be consistent with the State Health Plan established in 900 KAR 5:020.

(b) In determining whether an application is consistent with the State Health Plan, the cabinet, in making a final decision on an application, shall apply the latest criteria, inventories, and need analysis figures maintained by the cabinet and the version of the State Health Plan in effect at the time of the public notice of the application.

(c) In determining whether an application is consistent with the State Health Plan following a reconsideration hearing pursuant to KRS 216B.090 or a reconsideration hearing which is held by virtue of a court ruling, the cabinet shall apply the latest criteria, inventories, and need analysis figures maintained by the cabinet and the version of the State Health Plan in effect at the time of the reconsideration decision or decision following a court ruling.

(d) An application seeking to re-establish a licensed healthcare facility or service that was provided at the healthcare facility and which was voluntarily discontinued by the applicant shall be considered consistent with the State Health Plan under the

following circumstances:

1. The termination or voluntary closure of the former healthcare service or facility:

a. Was not the result of an order or directive by the cabinet, governmental agency, judicial body, or other regulatory authority;

b. Did not occur during or after an investigation by the cabinet, governmental agency, or other regulatory authority;

c. Did occur while the facility was in substantial compliance with applicable administrative regulations and was otherwise eligible for relicensure;

d. Was not an express condition of any subsequent Certificate of Need approval; and

e. Did not occur less than twenty-four (24) months prior to the submission of the application to re-establish;

2. The proposed healthcare service shall be provided within the same geographic service area as the former healthcare service;

3. The proposed healthcare facility shall be located within the same county as the former healthcare facility and at a single location; and

4. The application shall not seek to re-establish any type of bed utilized in the care and treatment of patients for more than twenty-three (23) consecutive hours.

(2) Need. The cabinet shall determine:

(a) If the applicant's ~~[has identified a need for the]~~ proposal for [in] the geographic service area defined in the application is consistent with criteria, inventories, and need analysis figures maintained by the cabinet and the State Health Plan, referenced in subsection 1 of this section, and the applicant has demonstrated that it is able to meet

1 the need identified by the criteria, inventories, and need analysis maintained by the
2 cabinet and the State Health Plan; or [;and]

3 (b) In the event the State Health Plan does not address the proposed health facility
4 or service, [If] the applicant has identified a need for the proposal for the geographic
5 service area defined in the application and has demonstrated that it is able to meet the
6 need identified [~~in the geographic service area defined in the application~~].

7 (3) Accessibility. The cabinet shall determine if the health facility or health service
8 proposed in the application will be accessible in terms of timeliness, amount, duration,
9 and personnel sufficient to provide the services proposed

10 (4) Interrelationships and linkages. The cabinet shall determine:

11 (a) If the proposal shall serve to accomplish appropriate and effective linkages with
12 other services, facilities, and elements of the health care system in the region and state;
13 and

14 (b) If the proposal is accompanied by assurance of effort to achieve comprehensive
15 care, proper utilization of services, and efficient functioning of the health care system.

16 (5) Costs, economic feasibility, and resource availability. The cabinet shall
17 determine:

18 (a) If it is economically feasible for the applicant to implement and operate the
19 proposal; and


20 (b) If applicable, if the cost of alternative ways of meeting the need identified in the
21 geographic area defined in the application would be a more effective and economical
22 use of resources.

23 (6) Quality of services.

- 1 (a) The cabinet shall determine if the applicant:
- 2 1. Is prepared to, and capable of undertaking and carrying out, the responsibilities
- 3 involved in the proposal in a manner consistent with appropriate standards and
- 4 requirements established by the cabinet; and
- 5 2. Has the ability to comply with applicable licensure requirements.
- 6 (b) Absence of an applicable licensure category shall not constitute grounds for
- 7 disapproving an application. (36 Ky.R. 237; Am. 807; eff. 10-21-2009.)

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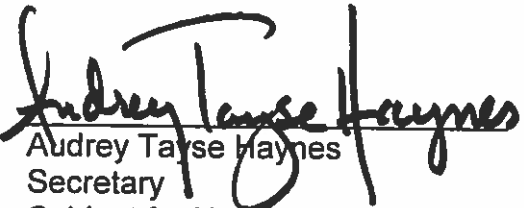
REVIEWED:



Emily Whelan Parento
Executive Director
Office of Health Policy

4/16/14
Date

APPROVED:



Audrey Tayse Haynes
Secretary
Cabinet for Health and Family Services

5/7/14
Date

900 KAR 6:070

PUBLIC HEARING AND PUBLIC COMMENT PERIOD:

A public hearing on this administrative regulation shall, if requested, be held on June 23, 2014, at 9:00 a.m. in Conference Suite B, Health Services Building, First Floor, 275 East Main Street, Frankfort, Kentucky 40621. Individuals interested in attending this hearing shall notify this agency in writing by June 16, 2014, five (5) workdays prior to the hearing, of their intent to attend. If no notification of intent to attend the hearing is received by that date, the hearing may be cancelled. The hearing is open to the public. Any person who attends will be given an opportunity to comment on the proposed administrative regulation. A transcript of the public hearing will not be made unless a written request for a transcript is made. If you do not wish to attend the public hearing, you may submit written comments on the proposed administrative regulation. You may submit written comments regarding this proposed administrative regulation until June 30, 2014. Send written notification of intent to attend the public hearing or written comments on the proposed administrative regulation to:

CONTACT PERSON: Tricia Orme, Office of Legal Services, 275 East Main Street 5 W-B, Frankfort, KY 40621, Phone: 502-564-7905, Fax: 502-564-7573, email: tricia.orme@ky.gov

REGULATORY IMPACT ANALYSIS AND TEIRING STATEMENT

Administrative Regulation Number: 900 KAR 6:070

Contact Person: Diona Mullins, (502) 564-9592

1. Provide a brief summary of:
 - (a) What this administrative regulation does: This administrative regulation establishes the guidelines for formal review of certificate of need applications.
 - (b) The necessity of this administrative regulation: This administrative regulation is necessary to comply with the content of the authorizing statutes, specifically KRS 216B.040(2)(a)1.
 - (c) How this administrative regulation conforms to the content of the authorizing statutes: This administrative regulation conforms to the content of the authorizing statutes by establishing the requirements necessary for consideration of certificate of need applications undergoing formal review.
 - (d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: This administrative regulation establishes the requirements necessary for consideration of certificate of need applications undergoing formal review.
2. If this is an amendment to an existing administrative regulation, provide a brief summary of:
 - (a) How the amendment will change this existing administrative regulation: The regulation is changed to clarify that in determining whether an application is consistent with the State Health Plan, the cabinet shall apply the latest criteria, inventories, and need analysis figures maintained by the cabinet and the version of the State Health Plan in effect at the time of the public notice of the application. When making a final decision following a reconsideration hearing pursuant to KRS 216B.090 or a reconsideration hearing which is held by virtue of a court ruling, the latest criteria, inventories, and need analysis figures maintained by the cabinet and the version of the State Health Plan in effect at the time of the reconsideration decision or decision following a court ruling shall be applied by the Cabinet. Also, Section 2(2) Need is revised to state that the Cabinet shall determine if the applicant's proposal is consistent with criteria, inventories, and need analysis figures maintained by the cabinet and the State Health Plan or in the event the State Health Plan does not address the proposal, the applicant has identified a need for the proposal in the geographic service area defined in the application.
 - (b) The necessity of the amendment to this administrative regulation: The amendment is necessary to clarify which documents will be relied upon

in making certificate of need decisions regarding consistency with the State Health Plan. Section 2(2) Need is revised to state that the Cabinet shall determine if the applicant's proposal is consistent with criteria, inventories, and need analysis figures maintained by the cabinet and the State Health Plan or in the event the State Health Plan does not address the proposal, the applicant has identified a need for the proposal in the geographic service area defined in the application.

- (c) How the amendment conforms to the content of the authorizing statutes: This administrative regulation establishes requirements necessary for consideration for formal review of certificate of need applications.
 - (d) How the amendment will assist in the effective administration of the statutes: This administrative regulation establishes requirements necessary for consideration for formal review of certificate of need applications.
- 3. List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: This administrative regulation affects an entity wishing to file a formal review certificate of need application. Annually, approximately 150 certificate of need applications are filed.
- 4. Provide an analysis of how the entities identified in question (3) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:
 - (a) List the actions that each of the regulated entities identified in question (3) will have to take to comply with this administrative regulation or amendment: A certificate of need application requesting formal review will be required to meet the requirements of this regulation.
 - (b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3): There will be no cost to entities to comply with this amendment.
 - (c) As a result of compliance, what benefits will accrue to the entities identified in question (3): Applicants will know the certificate of need application requirements for formal review.
- 5. Provide an estimate of how much it will cost the administrative body to implement this administrative regulation:
 - (a) Initially: No cost
 - (b) On a continuing basis: No cost
- 6. What is the source of the funding to be used for the implementation and enforcement of this administrative regulation: No funding is necessary since there is

no cost to implementing this administrative regulation.

7. Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an amendment: No increase in fees or funding is necessary.
8. State whether or not this administrative regulation established any fees or directly or indirectly increased any fees: This administrative regulation does not establish any fees and does not increase any fees either directly or indirectly.
9. TIERING: Is tiering applied? (Explain why or why not)
Tiering was not appropriate in this administrative regulation because the administrative regulation applies equally to all those individuals or entities regulated by it.

FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

Regulation No. 900 KAR 6:070

Contact Person: Diona Mullins

1. What units, parts or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation? Health care facilities owned by the state, county or city which submit certificate of need applications requesting formal review will be impacted by this regulation.

2. Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation. KRS 216B.040(2)(a)1 and KRS 216B.040(2)(a)2.

3. Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect.

(a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year? This amendment will not generate additional revenue for state or local government during the first year.

(b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years? This amendment will not generate additional revenue for state or local government during subsequent years.

(c) How much will it cost to administer this program for the first year? No additional costs are necessary to administer this program during the first year.

(d) How much will it cost to administer this program for subsequent years? No additional costs are necessary to administer this program for subsequent years.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Revenues (+/-):

Expenditures (+/-):

Other Explanation